



APPLICATION NO.

UNITED STATES PATENT AND TRADEMARK OFFICE

FILING DATE

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09/286,818 04/06/1999 RONALD L. REAM P99.0082 5472

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ART UNIT PAPER NUMBER

1615

FIRST NAMED INVENTOR

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/286,818	REAM ET AL.
	Examiner	Art Unit
	Pili A. Hawes	1615
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).
Status		
1) Responsive to communication(s) filed on <u>31 October 2005</u> .		
2a)⊠ This action is FINAL . 2b)□ This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) ⊠ Claim(s) 1-12,19-22 and 26-29 is/are pending i 4a) Of the above claim(s) is/are withdray 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) 1-12, 19-22, 26-29 is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or	vn from consideration.	
Application Papers		
9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction of the original transformation is objected to by the Examiner 11) The oath or declaration is objected to by the Examiner 12. **The oath or declaration is objected to by the Examiner 13. **The oath or declaration is objected to by the Examiner 14. **The oath or declaration is objected to by the Examiner 15. **The oath or declaration is objected to by the Examiner 16. **The oath or declaration is objected to by the Examiner 17. **The oath or declaration is objected to by the Examiner 18. **The oath or declaration is objected to by the Examiner 19. **The oath or declaration is ob	epted or b) objected to by the liderawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 		
Attachment(s)	_	
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	

DETAILED ACTION

Summary

Receipt of Applicant's Remarks filed 10-31-2005 is acknowledged. Claims 1-12 and 19-22 and 26-29 are pending in this action. As set forth in the previous office action, Claims 1-12 and 19-22 and 26-29 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 19-22 and 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants amend the claims to delete the phrase "less than the enteral administration amount" to recite "less than a typical amount of medicament that is swallowed by the individual to achieve a bioequivalent effect". This amendment is not sufficient to overcome the rejection as set forth in the previous office action or as set forth by the Board of Patent Appeals and Interference Decisions on Appeal mailed 09-10-2004.

The rejection is not overcome for the following reasons:

The Board as set forth on pages 4 and 5, describe various amounts of aspirin formulations. One of ordinary skill in the art would be aware that aspirin is used for the treatment of headaches as well as for preventing heart attacks, and the amount of

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aspirin for the treatment of these ailments vary. It is unclear what amount of aspiring fall with in the "less than typical amount" since one cannot determine the exact typical amounts of aspirin to treat headaches or heart conditions since this amount depends on age, weight, gender, and other factors that are patient and population dependent. Thus the metes and bounds of what a typical amount is, is not defined in a manner sufficient to make one of ordinary skill understand what amounts constitute a typical amount, thus the "less than typical amount" can also not be determined.

Likewise, the Board as set forth on page 6, discuss the specification example given as support for their being sufficient explanation of a "typical amount" using the chewing gum formulation with 50 mg of caffeine in comparison with the 100 mg oral tablet dosage. The Board set forth that "even assuming, therefore, that the 'typical amount' of caffeine administered is 100 mg, the specification provides no basis on which to extrapolate that dosage to other agents or medicaments." This argument is still applicable over the instant claims, even though applicants have added the phrase "that is swallowed by the individual to achieve a bioequivalent effect" because there is no basis for determining from the specification what the typical amount would be for all the various types of medicaments. Examiner notes that claim 1 recited a method of delivering a medicament. This is a generic term that encompasses all known medicaments. One of ordinary skill in the art would recognize that a typical dosage is determined based on many factors such as gender, age, weight, and medical conditions. Thus a typical amount for one patient population might be different than a typical amount from another patient population with differing sets of factors and

illnesses. Thus it is not within the level of one of ordinary skill to be able to determine what the various typical dosage amounts would be for all the medicaments known to man, as that amount would needs be determined based on the needs of the patient population being treated.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes Examiner-1615

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